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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,395	05/07/2001	Yasuo Sakai	SUD-001-USA-CIP	9441

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EXAMINER
NICKOL, GARY B

ART UNIT	PAPER NUMBER
1642	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/849,395	Applicant(s) SAKAI ET AL.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/780,086 .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-5 are pending and are currently under consideration.

Specification

The specification is objected to for multiple recitations of "zelatin". It appears that "zelatin" should be amended to "gelatin". Clarification or amendments are required.

The specification is further objected to for the following reason: The specification on page 1 should be amended to reflect the priority status of the present application. It is noted that applicants have updated the priority status to include reference to parent application serial No. 08/780,089 (Paper No. 7); however, applicants should further include reference to Japanese application No. 7-352918 filed December 27, 1995.

Claim Objections

Claim 1 is objected to for reciting "specially" as it appears that applicant's intended to recite "specifically". Clarification or amendments are requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1,5 are rejected under 35 U.S.C. 102(a) as being anticipated by Sakai Yasuo (JP 07082299, March 28, 1995, abstract). 102(b)

Sakai Yasuo teaches a method for producing a nonantigenic peptide composition comprising a decomposing step comprising specifically decomposing gelatin or collagen using collagenase to form a decomposed gelatin or collagen, and a purifying step comprising purifying the decomposed matter to obtain a nonantigenic peptide composition, wherein the nonantigenic peptide composition has a molecular weight of not more than 20,000 Da and an amino acid sequence of $(Gly\text{-}X\text{-}Y)_n$ where n is a natural number. Further, Sakai Yasuo teaches a nonantigenic peptide obtained by filtration wherein the nonantigenic peptide has a molecular weight greater than 0 and not more than 20,000 Da and having an amino acid sequence of $(Gly\text{-}X\text{-}Y)_n$ where n is a natural number.

Sakai Yasuo does not disclose the use of the peptide as a stabilizer, however the ability to function as a stabilizer would be an inherent property of the disclosed peptide. Further, the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A

composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982).

Sakai Yasuo further do not disclose that the nonantigenic peptide is obtained by gel filtration or by reversed phase chromatography. However, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case, the product *per se*, is a nonantigenic peptide whose molecular weight is greater than 0 and not more than 20,000 Da and having an amino acid sequence of $(Gly\text{-}X\text{-}Y)_n$ where n is a natural number.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerhard Quelle, German Patent No. 42 44 418 A 1, July 1, 1993).

G. Quelle teaches a method for producing a nonantigenic peptide composition comprising a decomposing step comprising specifically decomposing gelatin or collagen using collagenase to form a decomposed gelatin or collagen, and a purifying step comprising purifying the decomposed matter to obtain a nonantigenic peptide composition, wherein the nonantigenic peptide composition has an amino acid sequence of $(Gly\text{-}X\text{-}Y)_n$ where n is a natural number (see pages 4 and 20 of the English translation).

Further, G. Quelle teaches a nonantigenic peptide obtained by filtration wherein the nonantigenic peptide has an amino acid sequence of $(Gly\text{-}X\text{-}Y)_n$ where n is a natural number.

G. Quelle does not disclose the use of the peptide as a stabilizer. However the ability to function as a stabilizer would be an inherent property of the disclosed peptide. Further, the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982).

Further, G.Quelle do not disclose that the nonantigenic peptide is obtained by gel filtration or by reversed phase chromatography. However, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case, the product *per se*, is a nonantigenic peptide whose molecular weight is greater than 0 and not more than 20,000 Da and having an amino acid sequence of $(Gly\text{-}X\text{-}Y)_n$ where n is a natural number. Although, G.Quelle does not teach that the molecular weight of the peptide ranges between 0 and 20,000 Da, the claimed peptide appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by

the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Thakur *et al.* (Biopoplymers, Vol.25, 1986, pages 1081-1086).

Thakur *et al.* disclose collagen peptides which would have molecular weights of less than 20,000 Da and which meet the required formula of $(Gly\text{-}X\text{-}Y)_n$. The peptide composition of Thakur *et al.* is chemically synthesized while the instantly claimed composition recites a process of obtaining the peptides by gel filtration or by reversed phase chromatography after specifically decomposing gelatin or collagenase. However, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). Likewise, Thakur *et al.* do not recite the use of the peptide as a stabilizer, however the ability to function as a stabilizer would be an inherent property of the disclosed peptide. Further, the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai Yasuo (JP 07082299, March 28, 1995, abstract) in view of Current Protocols in Molecular Biology (Vol.2, Chapter 10, Pages 10.1.1- 10.18.6, 1990) or Gerhard Quelle, (German Patent No. 42 44 418 A 1, July 1, 1993) in view of Current Protocols in Molecular Biology (Vol.2, Chapter 10, Pages 10.1.1- 10.18.6, 1990).

Sakai Yasuo and or G.Quelle teach as set forth above.

Sakai Yasuo and or G.Quelle differ from the instant invention by not decomposing the composition by a column process, and by not purifying the composition by gel filtration or reversed phase chromatography.

Current Protocols teaches that column processes such as reversed phase chromatography are standard procedures known in the prior art for decomposing and purifying proteins (page 10.12.1, 10.0.7) and that gel filtration is also a common procedure known in the prior art for protein purification (page 10.9.1).

It would have been *prima facia* obvious to one of ordinary skill in the art at the time the invention was made and one would have been motivated to include a column process such as reverse phase chromatography for the purposes of decomposing and purifying the composition in the method taught by Sakai Yasuo (or G.Quelle) or to apply gel filtration to purify the composition taught by Sakai Yasuo (or G.Quelle) with a reasonable expectation of success as such decomposing and purification procedures were well known and standard procedures in the art as taught by Current Protocols.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
September 4, 2002